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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,857	12/12/2003	Martine Anne Cecile Wettendorff	B45198D1	1533
7590	06/18/2004		EXAMINER	
GLAXOSMITHKLINE Corporate Intellectual Property - UW2220 P.O. Box 1539 King Of Prussia, PA 19406-0939			SALIMI, ALI REZA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/734,857	WETTENDORFF, MARTINE ANNE CECILE	
<b>Examiner</b>		<b>Art Unit</b>	
A R Salimi		1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 02 April 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 December 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 10/070,479.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)              |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/2/04; 12/30/03</u> . | 6) <input type="checkbox"/> Other: _____.  |

## **DETAILED ACTION**

Claims 21-26 are pending.

Submitted Information Disclosure Statement (I.D.S) is noted.

### ***Response to Amendment***

The receipt of preliminary amendment of 12/12/2003, is acknowledged. Claims 1-20 have been canceled. Claims 21-26 have been added and are pending before the examiner.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

Claim 24 is essential duplicate of claim 1. The office cannot distinguish between the two products claimed. Please clarify.

### ***Claim Rejections - 35 USC § 112***

Claims 22, 23 and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing for recitation of "bulk of antigen", what does this mean? The claims have been interpreted in light of disclosure and since there is no standard given to one of ordinary skill in the art to decipher the metes and bounds of "bulk antigen", the claims are vague and indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Whittle et al (WO 96/26277).

The above cited reference taught admixture of HPV papillomavirus L1, including HPV-16, and HPV-18, in addition to aluminum hydroxide and MPL (see page 5, lines 28-31, page 8, lines 35-39, page 9, lines 13-21). Hence, the claims of 21-24 are clearly anticipated. Alternatively, it would have been obvious for one of ordinary skill in the art to take a well-known L1 protein of well-characterized HPV type and add the aluminum and MPL as taught by Whittle et al to induce an immunogenic response. The ordinary skill in the art would have been highly motivated by the above cited reference to use the adjuvant taught since the adjuvant push the response to TH1. One of ordinary skill in the art being familiar with the above cited art would not have anticipated any unexpected results as none have been provided. Therefore, the invention as deemed *prima facie* obvious absent unexpected results.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Bruck et al (WO 99/10375).

The above cited art taught a vaccine including HPV-16, and HPV-18 (see page 8) wherein L1 presented as virus like particles adsorbed on aluminum hydroxide and 3D-MPL (see page 9, lines 2-21). The claimed invention is directed to a product and the above cited art taught the same product; Applicant is reminded that the ratio limitation is design choice and does not carry patentable weight. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 21-26 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Whittle et al (US Patent No. 6,123,948).

The above cited reference taught admixture of HPV papillomavirus L1, including HPV-16, and HPV-18, in addition to aluminum hydroxide and MPL (see claims 15-21). Hence, Applicant's claims of 21-24 are clearly anticipated by the teaching and claims of the above cited patent. Alternatively for claims 25, and 26, it would have been obvious

for one of ordinary skill in the art to take a well-known L1 protein of well-characterized HPV type and add the aluminum and MPL as taught by Whittle et al to induce an immunogenic response. The ordinary skill in the art would have been highly motivated by the above cited reference to use the adjuvant taught since the adjuvant push the response to TH1. One of ordinary skill in the art being familiar with the above cited art would not have anticipated any unexpected results as none have been provided. Therefore, the invention as deemed *prima facie* obvious absent unexpected results.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 21-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Bruck et al (WO 99/10375).

The above cited art taught a vaccine including HPV-16, and HPV-18 (see page 8) wherein L1 presented as virus like particles adsorbed on aluminum hydroxide and 3D-MPL (see page 9, lines 2-21). The claimed invention is directed to a product and the above cited art taught the same product; Applicant is reminded that the ratio limitation is design choice and does not carry patentable weight. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volkin et al (US Patent No. 6,251,678 B1), and Thompson et al (Biochemical Society Transactions, 1997, 274S).

Volkin et al taught papillomavirus like particles including HPV-16, and HPV-18 and their mixture thereof. They also taught aluminum adjuvant (see the abstract, and claims). This differs only to the extent that they did not include MPL.

Thompson et al taught addition of MPL against human papillomavirus (HPV) late regions and taught specific antibodies raised against the HPV (see the entire page). This differs since they did not teach addition of aluminum adjuvant.

Therefore, one of ordinary skill in the art at the time of filing would have been motivated by to combine the aluminum and MPL with HPV regions specifically VLPs of HPV-16, and HPV-18 as taught by Volkin et al to induce an immunogenic response in a suitable host. One of skilled in the art being familiar with the above cited art would not have anticipated any unexpected results. Hence, the invention as a whole is *prima facie* obvious absent unexpected results.

No claims are allowed.

*Conclusion*

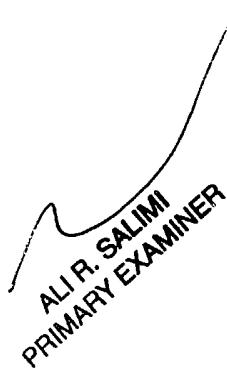
Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A. R. Salimi

6/17/2004



ALI R. SALIMI  
PRIMARY EXAMINER

A handwritten signature of "ALI R. SALIMI" is written in black ink. Below it, the words "PRIMARY EXAMINER" are printed in a smaller, sans-serif font.